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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/780,661	02/19/2004	Syed Rizvi	976	2178

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1611	

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07/23/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/780,661	RIZVI, SYED	
	Examiner	Art Unit	
	Isis A. Ghali	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 March 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413). Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicant's amendment and declaration, both filed 03/26/2008.

Claims 1-10 are pending and included in the prosecution.

The following rejection has been overcome by virtue of applicant's amendment and remarks:

The rejection of claims 1-10 under 35 U.S.C. 112, second paragraph, as being indefinite.

The following rejections have been discussed in details in the previous office action, and are maintained for reasons of record:

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-3, 5, 6, 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over the article "Compendium of Pharmaceutical Excipients for Vaginal Formulations" by Garg et al. by itself or combined with US 2002/0142690 ('690).

Garg et al. teach ideal vaginal formulation with desired characteristics in terms of safety, efficacy, patient compliance, aesthetic, acceptability to regulatory authorities, and cost requirements (page 14). Garg et al. teach towel to clean external vaginal area comprising lactic cid, water, potassium sorbate, O-9 (octoxynol-9), EDTA, cetylpyridinium chloride, and fragrance (page 17). Garg et al. further teach absorbent cotton in tampons as a carrier (top of page 18), and absorbent cotton tampon implies that it absorbs the composition applied to it to form impregnated substrate. Garg et al. teach amount of lactic acid is between 0.015 -6.6 %; amount of potassium sorbate is between 0.1-0.2%; amount of emulsifier can be as low as 0.3% for polyoxyethylene-polyoxypropylene copolymer, 0.5% for sodium lauryl sulfate, or 0.3-0.55 for cholesterol; amount of EDTA is between 0.01-0.1%; amount of preservative is between 0.01-0.02% (pages 18-22). Garg et al. teach alum potassium in the composition (page 18), claimed by applicant as odor absorbing agent.

Although Garg et al. teach all the ingredients of the product as instantly claimed, however, the reference does not explicitly teach the amount of the odor absorbing agent, or amount of antiseptic cetylpyridinium.

Garg et al. suggest the generic teaching of the amount of preservatives as low as 0.1-0.2% for benzoic acid that is known as antiseptic agent.

Although Garg et al. do not specifically teach the amounts of some ingredients as claimed by applicant, however, the amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide towel or tampon impregnated with the composition disclosed by Garg et al., and optimize the amounts of different ingredients in order to achieve the desired anti-infective effect and mean while maintaining pleasant odor of the composition.

Although Garg et al. implies the composition is absorbed into a substrate, however, Garg et al. does not explicitly teach the impregnation of the composition in the absorbent article.

US '690 teaches substrate of web fabric impregnated with composition comprising octooxynol-9, and deliver impregnated material upon wiping the contaminated surface, and avoid re-positioning the contaminant upon the surface which is being cleaned (abstract; paragraphs: 0023, 0025, 0029, 0031). The wipes can be handled safely, non-toxic, and even if misplaced poses little or no risk to the end user,

and far more effective at removing stubborn embarrassing contaminants helping preventing sexually transmitted diseases (paragraph 0034).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide towel or tampon comprising the composition disclosed by Garg et al., and optimize the amounts of different ingredients to obtain specific desired effect such as anti-infective effect, and further apply the composition to the towel or tampon by impregnation as disclosed by US '690, motivated by the teaching of US '690 that wipes impregnated with anti-infective composition can be handled safely, and even if misplaced poses little or no risk to the end user, and far more effective at removing stubborn embarrassing contaminants helping preventing sexually transmitted diseases, with reasonable expectation of treating vaginal contamination safely and effectively with reduction of the risk of transmitting sexually transmitted diseases using substrate impregnated with the composition disclosed by Garg et al.

Response to Arguments

3. Applicant's arguments filed 03/26/2008 have been fully considered but they are not persuasive.

Applicant argues that Grag et al. does not disclose treating vaginitis using the claimed composition and actually teaches away from the claimed method. The cited part of the reference is designated to cleanse the external vagina and not for treating vaginitis or valvuvaginitis.

In response to this argument, applicant's attention is directed to the scope of the present claims: claim 1 is product and claim 5 is method of treating vaginitis comprising one step of applying the claimed composition. All the elements of the product are disclosed by the Grag et al. by itself or combined with US '690. The claimed method requires one step of applying the composition to the affected body area, and Grag et al. disclosed that step. Grag et al. in page 15, at the bottom of the left column, stated that "Vaginal administration of drugs is mainly used for the treatment of local infections such as vaginitis, bacterial vaginosis, candidiasis and other infection". Further, Grag et al. in page 15, at the top of the right column, stated that: "Vaginally administered agents and formulations are mainly used and are being developed to provide protection against microbial infections." Therefore, treatment of vaginitis is the main goal of Grag's reference, and further disclosed many formulations to achieve such a goal. The composition used as cleansing for the skin is expected to have anti-infective effect to treat vaginitis because Grag et al. in page 15, right column, teaches that the ingredients normally used as excipients possess potent antimicrobial activities, and further listed surfactants as example. Therefore, the ingredients used to cleanse the skin as disclosed by Grag et al. are expected to provide antimicrobial activities. Additionally, cleansing the skin with wipe or towelette will remove materials attached to the surface of the skin including dirt, secretion and microbes that cause vaginitis. The ingredients disclosed by the reference as cleanser are expected to have anti-infective effect when applied to the vagina since materials and their properties are inseparable.

Regarding the argument, that the reference teaches away, it is argued that the disclosed examples and preferred embodiment do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). Treatment of vaginitis is the main goal of Grag's reference. It has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969).

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the claims would have been *prima facie* obvious within the meaning of 35 U.S.C. 103 (a).

Applicant argues that unexpected results have been shown to effectively control odor and the amount and type of odor absorbing agents are important features of the claimed invention without the use of fragrance, and Grag's reference requires fragrance.

In response to this argument, it is argued that the control of odor is expected from the composition disclosed by Grag et al. because they teach the same claimed composition, and materials and their properties are inseparable. Grag et al. disclosed

alum that is used by applicant as odor controlling agent. The claim language does not exclude the presence of fragrance. Additionally, elimination of an element and its function is obvious if the element is not desired. *Ex parte Wu* , 10 USPQ 2031 (Bd. Pat. App. & Inter. 1989). See also *In re Larson*, 340 F.2d 965, 144 USPQ 347 (CCPA 1965); and *In re Kuhle*, 526 F.2d 553, 188 USPQ 7 (CCPA 1975).

4. Claims 4 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garg et al., or over the combination of Garg et al. and US '690, and further in view of the article "Natural Deodorant" by Carrubba Inc.

The article "Natural Deodorant" by Carrubba Inc. was available before 11/13/2001, the date it was faxed to applicant. This implies that the article was available before that date 11/13/2001.

The teaching of Garg et al. by itself or combined with US '690 are discussed above. The teachings suggest all the ingredients in almost the claimed amounts.

However, Garg et al. by itself or combined with US '690 do not teach saccharomyces ferment as claimed by claims 4 and 7.

The article by Carrubba Inc. teaches saccharomyces ferment used as personal deodorant for feminine hygiene. The product is safe to be used on and around human and it is non-toxic, non-irritating, and non-allergenic (first page).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide towel or tampon impregnated with composition comprising the ingredients disclosed by Garg et al. by itself or combined with US '690,

and replace the fragrance element from the composition with saccharomyces ferment disclosed by Carrubba Inc., motivated by the teaching of the Carrubba article that saccharomyces ferment is safe to be used on and around human and it is non-toxic, non-irritating, and non-allergenic, with reasonable expectation of having substrate to be used on the genitalia impregnated with composition disclosed by Garg et al., and further comprising saccharomyces ferment that is deodorant for feminine hygiene articles and further is non-toxic, non-irritating, and non-allergenic that effectively, safely and pleasantly disinfect the site of wiping.

Response to Arguments

5. Applicant's arguments filed 03/26/2008 have been fully considered but they are not persuasive.

Applicant argues that the combination of the references does not teach all the elements of claim 4 and 7 and the claims are not obvious over the references because the specific quantity of odor controlling agent is not disclosed.

In response to this argument, it is argued that all the elements of the product claims are taught by the combined teachings of the prior art and the only step of the method claims is taught by the prior art. The article by Carrubba Inc. is relied upon for teaching the specific odor controlling agents claimed by claims 4 and 7. Carrubba Inc. teaches saccharomyces ferment used as personal deodorant for feminine hygiene. The product is safe to be used on and around human and it is non-toxic, non-irritating, and non-allergenic, and this teaching would have been motivated one having ordinary skill in

the art to include saccharomyces ferment in feminine personal hygiene products, with reasonable expectation of having substrate to be used on the genitalia impregnated with composition disclosed by Grag et al., and further comprising saccharomyces ferment that is deodorant for feminine hygiene articles and further is non-toxic, non-irritating, and non-allergenic that effectively, safely and pleasantly disinfect the site of wiping.

Regarding the amount of a specific ingredient in a composition, it is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention. The odor control is known property of saccharomyces ferment, and is not new and unexpected, and determination of its amount is within the ability of skilled artisan without undue experimentation in order to achieve the desired degree of odor control.

Applicants further argue that claims 4 and 7 contain “consisting essentially of” phrase, and the phrase limits the scope of a claim to the specified materials or steps "and those do not materially affect the basic and novel characteristics" of the claimed invention, and Grag's reference teaches sodium lactate and fragrance which are not recited by claims 4 and 7.

As applicant himself admits, the expression "consisting essentially of" limits the scope of the claim to the specified ingredients, and those that do not materially affect the basic and novel characteristics of the composition. *In re Janakirama-Rao*, 317 F 2d 951, 137 USPQ 893 (CCPA 1963). When applicant contends that modifying components in the reference's composition are excluded by the recitation of "consisting essentially of", applicant has the burden of showing the basic and novel characteristics of the claimed composition, i.e. showing that the introduction of these components would materially change the characteristics of applicant's composition. *In re De Lajarte,* 337 F 2d 870, 143 USPQ 256 (CCPA 1964). Additionally, elimination of an element and its function is obvious if the element is not desired. *Ex parte Wu* , 10 USPQ 2031 (Bd. Pat. App. & Inter. 1989). See also *In re Larson*, 340 F.2d 965, 144 USPQ 347 (CCPA 1965); and *In re Kuhle*, 526 F.2d 553, 188 USPQ 7 (CCPA 1975). Odor controlling agent and fragrance are both added to personal care products to eliminate undesired odors, and it is personal choice to select either or both in the product according to intended use.

Response to Amendment

6. The declaration under 37 CFR 1.132 filed 03/2/2008 is sufficient to overcome the rejection of claims 1-10 based upon obviousness rejection over Grag et al. by itself or combined with US '690, and further in view of Carrubba as applied to claims 4 and 7.

The declaration refer(s) only to the system described in the above referenced application and not to the individual claims of the application. Thus, there is no showing

that the objective evidence of nonobviousness is commensurate in scope with the claims. See MPEP § 716. The present claims are directed to product and method of its use to treat vaginitis, and the declaration is directed to reduction of odor without the use of fragrance. The declaration showed that the claimed product controlled odor, and does not provide side by side comparison of fragrance with odor controlling agents in order to show the superior unexpected results. The cited prior art disclosed the claimed odor controlling agent, and showed some embodiments without fragrance. In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Isis A Ghali/
Primary Examiner, Art Unit 1611

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